UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,361	06/20/2005	Hubert Eng	AREX-P01-015	6278

28120 7590 09/04/2007

ROPES & GRAY LLP
PATENT DOCKETING 39/41
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,361	ENG ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed October 5, 2004 is acknowledged and has been entered.

2. Claims 1-35 are pending in this application and are currently subject to restriction.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 10, insofar as the claim is drawn to a method for treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-1 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

Group II, claim 10, insofar as the claim is drawn to a method for treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-2 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

Group III, claim 10, insofar as the claim is drawn to a method for treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b)

administering an Alt-3 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

Group IV, claim 10, insofar as the claim is drawn to a method for treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-4 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

Group V, claim 10, insofar as the claim is drawn to a method for treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-5 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

Group VI, claims 20 and 34, insofar as the claims are drawn to a packaged pharmaceutical or kit comprising (a) an Alt-1 antibody, and (b) instruction for use.

Group VII, claims 20 and 34, insofar as the claims are drawn to a packaged pharmaceutical or kit comprising (a) an Alt-2 antibody, and (b) instruction for use.

Group VIII, claims 20 and 34, insofar as the claims are drawn to a packaged pharmaceutical or kit comprising (a) an Alt-3 antibody, and (b) instruction for use.

Group IX, claims 20 and 34, insofar as the claims are drawn to a packaged pharmaceutical or kit comprising (a) an Alt-4 antibody, and (b) instruction for use.

Group X, claims 20 and 34, insofar as the claims are drawn to a packaged pharmaceutical or kit comprising (a) an Alt-5 antibody, and (b) instruction for use.

4. Claims 1-9 and 11-13 are linking claims, linking the inventions of Groups I-V; and claims 14-19, 21-33 and 35 are linking claims, linking the inventions of Groups VI-X. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. The technical feature recited in claim 1 is a method comprising the steps of providing (a) administering one or more agents that cause apoptosis of target cells; and (b) administering an antibody immunoreactive with an antigen on said target cells, wherein said antibody is cytotoxic to said target cells.. This claim lacks an inventive step over Slamon et al (NEJM, 344(11):783-792, 2001). Slamon et al teach administering to breast cancer patients the chemotherapeutic, paclitaxel, which causes apoptosis in breast cancer cells and the antibody Trastuzumab, which recognizes the HER2 antigen on the breast cancer cells and is cytotoxic to said cells (see entire document, e.g., abstract). Since Slamon et al teach

the technical feature recited in claim 1, it is not a special technical feature and the groups do not relate to a single general inventive concept as required under PCT Rule 13.1. Furthermore, at page 13 of the specification, the antibodies designated Alt-1 through Alt-5 are disclosed as binding structurally distinct antigens that are presumed to not be linked by unity of invention. For example, the specification discloses at page 13, second paragraph that the ALT-1 antibody specifically binds the tumor antigen MUC-1, while the ALT-2 antibody binds the tumor antigen CAI CA125.

For these reasons, the special technical feature of the invention of Group I is treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-1 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells..

The special technical feature of the invention of Group II is treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-2 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

The special technical feature of the invention of Group III is treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-3 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

The special technical feature of the invention of Group IV is treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a) administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-4 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

The special technical feature of the invention of Group V is treating a patient to reduce proliferation of and/or kill target cells that express an antigen, comprising (a)

administering one or more agents that cause apoptosis of the target cells; and (b) administering an Alt-5 antibody immunoreactive with said antigen, and wherein said antibody is cytotoxic to said target cells.

The special technical feature of the invention of Group VI is making a packaged pharmaceutical or kit comprising (a) an Alt-1 antibody, and (b) instruction for use.

The special technical feature of the invention of Group VII is making a packaged pharmaceutical or kit comprising (a) an Alt-2 antibody, and (b) instruction for use.

The special technical feature of the invention of Group VIII is making a packaged pharmaceutical or kit comprising (a) an Alt-3 antibody, and (b) instruction for use.

The special technical feature of the invention of Group IX is making a packaged pharmaceutical or kit comprising (a) an Alt-4 antibody, and (b) instruction for use.

The special technical feature of the invention of Group X is making a packaged pharmaceutical or kit comprising (a) an Alt-5 antibody, and (b) instruction for use.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

6. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.** The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

bd
August 30, 2007